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DATE MAILED: 12/02/2003

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/981,123 10/16/2001 James L. Holloway 99-88C1 6433 **EXAMINER** 12/02/2003 Phillip B.C. Jones, J.D., Ph.D. FRONDA, CHRISTIAN L ZymoGenetics, Inc. ART UNIT PAPER NUMBER Patent Department 1201 Eastlake Avenue East 1652 Seattle, WA 98102

Please find below and/or attached an Office communication concerning this application or proceeding.

		<del></del>	<del></del>				
Office Action Summary		Application	tion No. Applicant(s)				
		09/981,123	3	HOLLOWAY, JAMES L.			
Office Action Summary			Examin r		Art Unit		
The MAN INO DATE of this communication com		Christian L		1652			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status							
1)	Responsive to communication(s) f	iled on	.•				
2a) <u></u> ☐	This action is <b>FINAL</b> .	2b)⊠ This a	ction is no	n-final.			
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disp sition of Claims							
4)⊠ Claim(s) <u>1-20</u> is/are pending in the application.							
	4a) Of the above claim(s) is/are withdrawn from consideration.						
	5) Claim(s) is/are allowed.						
•	6) Claim(s) is/are rejected.						
· · · · · · · · · · · · · · · · · · ·	7) Claim(s) is/are objected to.						
8) Claim(s) <u>1-20</u> are subject to restriction and/or election requirement.							
Application Papers							
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. §§ 119 and 120							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.							
13) 🗌 A	Acknowledgment is made of a claim	for domestic	priority un	der 35 U.S.C. § 119	(e) (to a provisional ap		
since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.							
a) ☐ The translation of the foreign language provisional application has been received.							
14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.							
Attachmen	ıt(s)						
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413) Paper No(s)							
	ce of Draftsperson's Patent Drawing Review mation Disclosure Statement(s) (PTO-1449)	•		·	Patent Application (PTO-15		

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## **DETAILED ACTION**

## Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6 and 20, drawn to an isolated serine protease, classified in class 435, subclass 219.
  - II. Claims 7-15, drawn to an isolated nucleic acid, a vector, a recombinant host cell, an method of producing Zfaix1 protein, classified in class 435, subclass 69.1.
  - III. Claims 16 and 19, drawn to an antibody, classified in class 530, subclass 387.1.
  - IV. Claim 17, drawn to a method of detecting the presence of *Zfaix1* gene expression in a biological sample using nucleic acid probes, classified in class 435, subclass 6.
  - V. Claim 18, drawn to a method of detecting the presence of Zfaix1 in a biological sample using antibodies, classified in class 435, subclass 7.1.
- 2. The inventions are distinct, each from the other because of the following reasons:
  Inventions of Groups I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The polypeptide of Group I, the polynucleotide of Group II, and the antibody of Group III are independent chemical entities and require different literature searches.

The inventions of Groups I and II are unrelated to the inventions of Groups IV and V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the processes of Groups IV and V do not require the products of Group I or Group II.

The invention of Group III is unrelated to the inventions of Group IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The process of Group IV does not require the product of Group III.

The invention of Group III is related to the invention of Group V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the antibody in a process for purifying and isolating the Zfaix1 serine protease from a biological source.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

- 3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

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**CLF**